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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,816	05/03/2005	Tarja Suomalainen	227-159	7841

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,816	SUOMALAINEN ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/3/05; 7/18/05; 8/11/05; 10/14/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendments to the claims filed with the office on Feb 6th 2006 is duly acknowledged.

Claims 1-8 (group I) have been withdrawn from further considerations.

Claims 9-17 (currently amended group II, and newly added claims 10-17) are examined on their merits, herein.

Election/Restrictions

Applicant's election with traverse of group II (claim 9, and newly presented claims 10-17) in the reply filed on Feb 6th 2006 is acknowledged. The traversal is on the ground(s) that "although the inventions identified by the examiner are separately patentable, both the need for compact prosecution and the public interest would be served by examination of all of the claims in a single application" and since the product of both processes is the same, the search would not constitute an undue burden on the examination process (see applicant's remarks, page 5, in particular). This is not found persuasive because burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, scope of enablement, and double patenting issues. Moreover, the inventions of groups I and II are still deemed to lack unity because the special technical feature i.e. the composition comprising microorganisms (as recited in claim 1 and currently amended claim 9) have been know in the prior art (see rejections as set forth below), and a person of ordinary skill would be motivated to combine the microorganisms to arrive at

the invention as claimed. Therefore, instant claims lack unity of invention. Claims 1-8 (the invention of group I) are hereby withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 9-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev et al (Arch, Fam. Med., 1996, 5: 593-596; IDS) in view of Reid (Am. J. Clin. Nutr., 2001, 73: 437S-443S; [U]), Mayra-Makinen et al (US Patent 5,378,458; IDS) or Suomalainen et al (Lait, 1999, 79: 165-174; IDS), and as supported by American Type Culture Collection (ATCC, 1996; [V]).

Claims are directed to **a method for inhibiting the growth of yeasts** and for relieving **yeast-related symptoms** in animals or humans, the method comprising administering the microbes ***Lactobacillus rhamnosus*** LGG, ATCC 53103, ***Lactobacillus casei*** ssp. *rhamnosus* LC705, DSM 7061, and ***Propionibacterium freudenreichii*** ssp. *shermanii* PJS, DSM 7067 to an individual in need thereof in an

amount sufficient to produce the desired effect (claim 9); wherein the microbes are administered in the form of a product of the **food industry** or the pharmaceutical industry, a health promoting product, or a natural product containing said microbes (claim 10); wherein the microbes are administered in the form of a **food product** containing said microbes (claim 11); wherein the microbes are administered in the form of a **dairy product** containing said microbes (claim 12); wherein the product containing said microbes **in addition** contains conventional **(starter) bacteria** (claim 14); wherein the microbes are administered in the form of a **unit dosage form** containing the microbes (claim 15); wherein the microbes are administered in the form of a **oral** unit dosage form containing the microbes (claim 16).

Shalev et al (IDS) teach a method for inhibiting the growth of yeast and for relieving yeast-related symptoms (such as recurrent candidal vaginitis and bacterial vaginosis) in individuals in need thereof (such as human subjects, women) in an amount sufficient to produce the desired effect by oral administration of a dairy product (i.e a food product) such as yogurt (a unit dose of 150 ml of the yogurt preparation) containing microbes such as *Lactobacillus acidophilus* (a hydrogen peroxide producing strain; one of the well known probiotic lactic acid bacteria used both orally and intravaginally for such treatments; see Shalev et al, pages 593-594, patients & methods, results; page 596, comment; and references therein).

It is noted that the specific genus and species of the bacteria as recited in the method claim 1 have been classified and denoted by skilled artisans in this art with various alternative names; for example *Lactobacillus rhamnosus* has also been cited by the persons of skill as *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus casei ssp. rhamnosus*, *Lactobacillus delbrueckii*, *and Lactobacillus helveticus* (as evident by the disclosure from ATCC, 1996, page 197, in particular). Similarly, *Propionibacterium freudenreichii* has also been cited by persons of skill in the art as *Propionibacterium*

shermanii (as evident by the disclosure of ATCC, 1996, page 272, left column, in particular).

However, a method for inhibiting the growth of yeasts and for relieving yeast-related symptoms in animals or humans comprising administering a composition containing three specific strains of bacteria (as recited in claim 1) has not been explicitly taught by the method of Shalev et al.

Reid [U] teaches the use of probiotic agents (by oral administration/ingestion) such as lactic acid bacteria (LAB; for example *Lactobacillus* GG, ATCC 53103; see Reid, figure 2, page 439S, left column, page 441S, left column, 1st paragraph, and references therein, in particular) in prophylactic and therapeutic treatment of urogenital tract infections that include candidal (yeast) vaginitis and related symptoms (UTI; see Reid, abstract, page 437S, in particular).

Mayra-Makinen et al (IDS) teach a composition (a substitute for chemical preservatives/additives, i.e. natural biopreservatives) comprising LAB strain *Lactobacillus casei* ssp. *rhamnosus* LC705, DSM 7061 and a propionic acid bacterium (PAB) such as *Propionibacterium freudenreichii* ssp. *shermanii* PJS, DSM 7067 with or without other LAB such as *Lactobacillus casei* (see Mayra-Makinen et al, abstract, claims, column 2, summary of the invention, in particular) for inhibiting growth of yeast and moulds. Although, the invention of Mayra-Makinen et al does not disclose the use of such composition containing said microbes for relieving yeast-related symptoms in an individual in need thereof, the fact that a combination of certain LAB and PAB (see specific strains as discussed supra) strains was much more effective in inhibiting yeast

and mould growth (and thus has specific utility in the food industry) is, nevertheless, disclosed by the referenced invention. Mayra-Makinen et al also teach the inclusion of other LAB strains in combination with the LC 705 DSM 7061 strain to improve the effectiveness in terms of growth inhibition of yeast and moulds (see column 2, 2nd paragraph, in particular).

Suomalainen et al (IDS) disclose the strains of LAB (such as *Lactobacillus casei* ssp. *rhamnosus* LC705, DSM 7061) and the strain of PAB such as *Propionibacterium freudenreichii* ssp. *shermanii* PJS, DSM 7067 as protective cultures and their use as biopreservatives against food spoilage yeasts, moulds, and *Bacillus* spp., alone and in combination in order to improve the self life of fermented milks and bread by effectively inhibiting the growth of yeast and moulds (see abstract, introduction, materials & methods, and discussion, in particular). Suomalainen et al disclose the use of conventional starter cultures (see page 166, right column, in particular) that were added with the protective microbes used for inhibiting the growth of yeast and moulds, and also demonstrate the fact that the protective cultures did not interfere with the basic starter microbes in yogurt during the yogurt manufacture (see Suomalainen et al, page 173, 1st paragraph, in particular).

It would have been obvious for a person of ordinary skill in the art at the time this invention was made to modify the method for inhibiting yeast growth and for relieving yeast-related symptoms as taught by Shalev et al or Reid using the LAB and its specific strain such as *Lactobacillus* GG, ATCC 53103 to further include the strains of LAB (such as *Lactobacillus casei* ssp. *rhamnosus* LC705, DSM 7061) and PAB (such as

Propionibacterium freudenreichii ssp. *shermanii* PJS, DSM 7067) as explicitly disclosed by the inventions of Mayra-Makinen et al or Suomalainen et al.

The person of ordinary skill in the art would have been motivated to use the microbes as taught by Shalev et al or Reid in combination with the microbes disclosed by Mayra-Makinen et al or Suomalainen et al for inhibiting yeast growth and for relieving yeast-related symptoms because both Mayra-Makinen et al and Suomalainen et al have **demonstrated the benefits such as the growth inhibiting effects** of this bacterial combination (i.e. strains *Lactobacillus casei* ssp. *rhamnosus* LC705, DSM 7061 and *Propionibacterium freudenreichii* ssp. *shermanii* PJS , DSM 7067) on yeasts and moulds, albeit for use in the food industry as natural biopreservative to avoid food spoilage.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success when modifying the method of Shalev et al or Reid by including the microbial strains for inhibiting yeast growth as disclosed by Mayra-Makinen et al or Suomalainen et al as it offers addition benefits in terms of providing an effective combination of microbes for the inhibition of yeasts that would make the method of Shalev et al or Reid much more effective in treating yeast related symptoms when administered orally in individuals in need thereof.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

2. Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalev et al (IDS), Reid [U], Mayra-Makinen et al (IDS) or Suomalainen et al (IDS), and as supported by American Type Culture Collection [V], as applied to claims 9-12 and 14-16, and further in view of Vinderola et al (J. Dairy Sci., 2000, 83: 1905-1911; [W]) and Simons et al (Caries Res., 1997, 31:91-96; IDS).

Claims 13 and 17 are generally directed to a method of claim 12, wherein the microbes are administered **in cheese** containing said microbes; and a method according to claim 16, wherein the oral unit dosage form is **a capsule or a tablet containing xylitol** in addition to the microbes.

The teachings of Shalev et al (IDS), Reid [U], Mayra-Makinen et al (IDS) or Suomalainen et al (IDS; as supported by American Type Culture Collection [V]) as applied to claims 9-12 and 14-16 are discussed above, and are further relied upon in the same manner. The oral administration of probiotic microorganisms (such as LAB) contained in a dairy product (i.e. yogurt) have been explicitly disclosed by the invention of Shalev et al (and also reviewed by Reid).

However, a method wherein the microbes are administered in cheese containing said microbes, and wherein the oral unit dosage form is a capsule or a tablet containing xylitol in addition to the microbes, is not explicitly disclosed by the inventions of Shalev et al (IDS), Reid [U], Mayra-Makinen et al (IDS) or Suomalainen et al (IDS; as supported by American Type Culture Collection [V]).

Vinderola et al [W] teach the viability of probiotic bacteria (such as *Lactobacillus acidophilus* and *Lactobacillus casei*) along with the nonprobiotic microflora in Argentinian Fresco Cheese in order to be used as a suitable carrier for probiotic

cultures selected for their health-promoting properties (see Vinderola et al, page 1905, abstract, introduction, conclusions, page 1910, and references therein, in particular).

Simon et al (IDS) teach the use of xylitol (a sweetener) in a clinical trial in elderly patients administered orally with or without a chemotherapeutic agent (such as chlorhexidine) in order to study the antibacterial effect of chlorhexidine/xylitol chewing-gum on cariogenic salivary microflora (see Simon et al, abstract, page 91, and discussion, page 94, right column, 1st paragraph, in particular).

At the time this invention was made, it would have been obvious to a person of ordinary skill in the art to substitute the unit dosage form (i.e. the dose form of the yogurt enriched with the microbes) used for the administration of probiotic microbes (of the inventions as disclosed by Shalev et al, Reid [U], Mayra-Makinen et al or Suomalainen et al, and as supported by American Type Culture Collection [V]) with the form of a food product such as cheese, or with the unit dosage form of a capsule or tablet containing xylitol as a sweetener, as explicitly taught by the inventions of Vinderola et al and Simons et al, respectively.

The person of ordinary skill in the art would have been motivated to substitute the unit dosage form as disclosed by Vinderola et al and Simons et al because they teach the benefits of using such unit dosage forms (for example, in the form of a health-promoting food product suitable for nutrition, that induces both antibacterial as well as compounds like xylitol as sweetener for salivary stimulation in individuals/patients in need thereof; see discussion, supra) in the delivery of probiotic microbes and drugs in

individuals in need thereof, and provide the disclosure for the suitability of such unit dosage forms.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success when substituting the unit dosage form of Shalev et al (in view of the disclosures of Reid, Mayra-Makinen et al or Suomalainen et al, as supported by American Type Culture Collection) with the unit dosage forms taught by Vinderola et al and Simons et al (see discussion supra) because they have successfully demonstrated the use of such dosage forms for delivery of probiotic microbes and/or drugs in order to have antimicrobial effects, or to provide stimulatory effect on saliva in patients in need thereof.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/470,151 (common applicants, same assignee, Valio Ltd. Finland). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in 10/470,151 are drawn to a composition and method of use comprising at least two, or at least three of the microorganisms, since the instant method uses a composition comprising microbes which are the same, the scope of the claimed inventions are coextensive, and thus necessitate an obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyendra K. Singh
Patent Examiner
Art Unit 1651
Phone: 571-272-8790

JEAN C. WITZ
PRIMARY EXAMINER